

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/809,468	Confirmation No. 5503
Applicants	:	Michael Wholey et al.	
Filed	:	March 15, 2001	
Title	:	METHOD AND APPARATUS FOR MEDICAL DEVICE FOR ASPIRATION OF THROMBOEMBOLIC DEBRIS	
TC/A.U.	:	3761	
Examiner	:	Leslie R. Deak	
Docket No.	:	MICW 48751	
Customer No.	:	29694	

AMENDED APPEAL BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

June 25, 2008

Sir:

This paper is submitted in response to the Notification of Non-Compliant Appeal Brief mailed June 20, 2008. Appellants hereby appeal the rejection of the captioned case set forth in the Office Action dated January 22, 2007.

REAL PARTY IN INTEREST

The real parties in interest are Michael Wholey, Mark H. Wholey and Petra Wholey, the inventors of the captioned application.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences that are believed to directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1-7 are rejected. Claims 12-21 are withdrawn. Claims 8-11 are objected to. Claims 1-11 are appealed.

Claims 1-5 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over U.S. Pat. No. 4,406,786 to Hein in view of U.S. Pat. No. 4,399,042 Stannard et al.

Claim 6 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hein '786 in view of Stannard et al. '042 in view of U.S. Pat. No. 6,059,745 to Gelbfish.

Claim 7 stands rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Hein '786 to in view of Stannard et al. '042 in view of Gelbfish '745 in further view of U.S. Pat. No. 6,416,665 to McGrath.

Claims 8-11 stand objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims.

A listing of the appealed claims is presented in the Appendix.

STATUS OF AMENDMENTS

There are no outstanding amendments.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to an apparatus for collecting blood clots, plaque, and other debris in arteries or veins. The apparatus includes a filter assembly forming an elongated chamber 23, a paddle assembly 25, 26 disposed in the chamber 23 having at least one paddle 25 having front and rear exterior surfaces defining a thickness of the paddle 25 and pores 27 extending through the thickness of the paddle from the front surface to the rear surface of the paddle 25, a porous floor 29 disposed within and extending across the chamber 23, and a means for coupling the filter assembly to an artery and/or to a vein.

Regarding the filter assembly as recited in Claim 1, one or more examples can be found in Figs. 5-9 which are described in paragraphs [0027] through [0030] of the specification. Examples of an elongated chamber 23, paddle 25, pores 27 and porous floor 29 can be found in Figs. 5-7 which are described in the specification at paragraphs [0028] through [0030]. An example of a means for coupling the filter assembly to an artery and/or vein is illustrated by the tubing 21, 33 shown in Fig. 6 which is described in the specification at paragraphs [0027] through [0028].

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether Claims 1-5 are unpatentable under 35 U.S.C. 103(a) over Hein '786 in view of Stannard et al. '042.

Whether Claim 6 are unpatentable under 35 U.S.C. 103(a) over Hein '786 in view of Stannard et al. '042, further in view of Gelbfish '745.

Whether Claim 7 are unpatentable under 35 U.S.C. 103(a) over Hein '786 in view of Stannard et al. '042 in view of Gelbfish '745 further in view of McGrath.'665.

ARGUMENT

Rejection of Claims 1-5 under 35 U.S.C. 103(a) as allegedly unpatentable over Hein '786 to in view of Stannard et al. '042

Applicants respectfully submit that the applied prior art references do not render obvious all of the claimed limitations under 35 U.S.C. § 103(a). Claims 1-5 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hein '786 in view of Stannard et al. '042. The final Office Action acknowledges that Hein '786 fails to disclose an apparatus with porous paddles. Stannard et al. '042 is relied upon as teaching a filter apparatus with a porous filter bed (26) and paddles or blades (44) that agitate the fluid in the filter chamber and scrape the particulate material from the filter bed. The final Office Action recites that:

The paddles have a front and a back surface (see FIG 6) and horizontal holes 160 drilled in the blade 152 (see FIG 10) in order to assist in removal of filter cakes from the apparatus (see column 6, lines 15-20).

The Office Action of June 22, 2007 further states that:

Stannard clearly illustrates a paddle or blade 152 that comprises a thickness (see FIG 6), with pores 160 that extend through the thickness (see FIG 10), meeting the limitations of the claims.

According to the Examiner:

it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the agitating means or paddles disclosed by Hein with porous surfaces and a rotator shaft as disclosed by

Stannard in order assist in removal of filter cakes from the apparatus, as taught by Stannard (see column 6, lines 15-20).

The Advisory Action further states that:

Applicant further argues that the porous blades disclosed by Stannard fail to meet the requirements of claim 1. Applicant asserts that the paddle of Stannard defines a front surface 154 and rear surface 156, and holes do not extend from the front to the rear. However, examiner never set forth such an interpretation of the front and rear surfaces of the paddle. In fact, Stannard discloses that the view of the blades in FIG 6 is a plan, or overhead view, and the paddle shown in FIG 10 is a lateral view. The lateral view illustrates that the holes 160 extend laterally through the plate of the scraper blade. Applicant's arguments conflict with the plain disclosure of the reference.

The Examiner has failed to explain where in the apparatus of Stannard et al.

'042 the following elements are located: (1) the front surface of a paddle or blade; (2) the rear surface of the paddle or blade; (3) the thickness of the paddle or blade; and (4) pores extending through the thickness from the front surface to the rear surface of the paddle or blade.

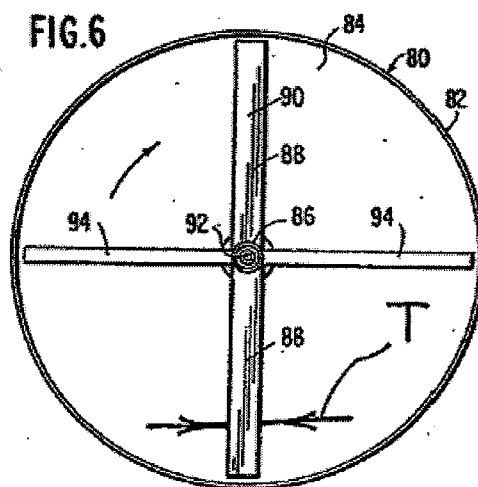
Hein '786 discloses a laboratory pressure filtering device for fluids which includes a small magnetic stirrer driven by a rotating magnet underneath the filtration unit. Stannard et al. '042 discloses a filtering device for wastewater treatment sludges including a rigid filter bed and a scraper blade assembly which rotates above the filter bed to lift portions of filter cake from the bed. In the embodiments shown in Figs. 7-10 of Stannard et al. '042, the scraper blades include at least one porous plate and an underlying chamber in the blade in which a vacuum is applied to remove liquid from the filter cake that is deposited on the porous plate. In the embodiments shown in Figs. 8-10 of Stannard et al. '042, the scraper blades also have horizontal holes and vertical holes, e.g. see items 160 and 162 of Fig. 10 of Stannard et al. '042.

The combination of Hein '786 and Stannard et al. '042 proposed by the Examiner would not result in the presently claimed apparatus because if the scraper design taught by Stannard et al. '042 was used in place of the magnetic stirrer 5 of Hein '786, such a combination would not include a paddle assembly as recited in Claim 1 comprising at least one paddle having front and rear exterior surfaces defining a thickness of the paddle and pores

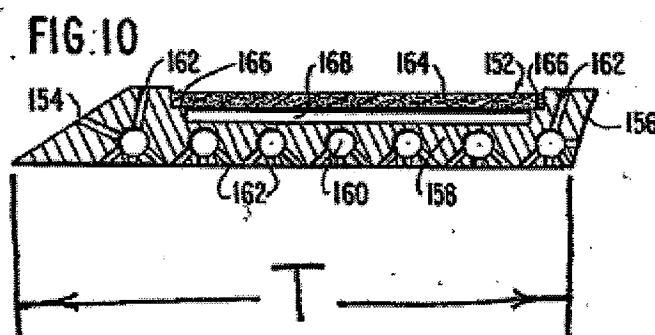
extending through the thickness of the paddle from the front surface to the rear surface of the paddle.

Fig. 6 of Stannard et al. '042 is a top view of a filter apparatus including two scraper blades 88 which rotate in a cylindrical tank 82. The Examiner generally states that the blades shown in Fig. 6 have a front and a back surface without explaining exactly where those surfaces are, and relies on Fig. 6 as showing the thickness of each blade. The Examiner relies on Fig. 10 of Stannard et al. '042 as showing horizontal holes 160 drilled in a blade 152 but does not state the relevance of the holes 160. It does not appear that either of these elements alone or in combination meets the limitation recited in Claim 1 of pores extending through the thickness of the paddle from the front surface to the rear surface of the paddle.

Fig. 6 of Stannard et al. '042 is illustrated below. The Examiner states that the blades shown in Fig. 6 have a front and a back surface, and relies on Fig. 6 as showing the thickness of each blade. According to the Examiner, the front exterior surface of the paddle as presently claimed corresponds to the front or leading blade surface shown in Fig. 6 of Stannard et al. '042, the rear exterior surface of the paddle as presently claimed corresponds to the back or trailing blade surface shown in Fig. 6, and the thickness of the paddle as presently claimed corresponds to the distance between the front and back blade surfaces shown in Fig. 6. Fig. 6 of Stannard et al. '042 is reproduced below, with the thickness of the blade 88 as defined by the Examiner drawn in and labeled as "T".



The Examiner relies on Fig. 10 of Stannard et al. '042 as showing horizontal holes 160 drilled in a blade 152. According to the Examiner, the pores 160 extend through the thickness of the blade 152, and thus meet the limitations of Claim 1. As shown in Fig. 10 and described at column 6, lines 15-25 of Stannard et al. '042, the scraper blade 152 has a front or scraper end 154 and a back or trailing end 156. Based upon the Examiner's definition of the thickness of the blade noted above, the thickness of the blade 152 shown in Fig. 10 is defined as the distance between the front 154 and back 156 of the blade. Fig. 10 of Stannard et al. '042 is reproduced below, with the thickness of the blade 152 drawn in and labeled as "T".



The hole 160 of Stannard et al. '042 does not extend through the thickness of the blade from its front surface to its back surface. Instead, the hole 160 extends radially outwardly along the blade, and does not extend from a front to a rear surface of the blade.

Applicants submit that one skilled in the field of medical devices as presently claimed would not look to the field of laboratory pressure filtering devices of Hein '786 or the field of wastewater treatment sludge filters of Stannard et al. '042 for possible teachings or suggestions as to the design of medical device filters.

Moreover, even if Hein '786 and Stannard et al. '042 could be properly combined as suggested by the Examiner, such a combination would not result in the presently claimed apparatus. For example, even if the scraper design taught by Stannard et al. '042 was used in place of the magnetic stirrer 5 of Hein '786, such a combination would not include a paddle assembly as recited in Claim 1 comprising at least one paddle having front and rear

exterior surfaces defining a thickness of the paddle and pores extending through the thickness of the paddle from the front surface to the rear surface of the paddle.

A *prima facie* case of obviousness has not been established because the Examiner has not identified any front or rear surfaces of a blade that define a thickness of the blade, in combination with pores that extend from the front surface to the rear surface through the thickness of the blade. Moreover, it is submitted that Hein '786 and Stannard et al. '042 are non-analogous art that do not apply to an apparatus for collecting blood clots, plaque, and other debris in arteries or veins. Therefore, the rejection of Claim 1 and the claims that depend therefrom based on Hein '786 in view of Stannard et al. '042 is improper and should be withdrawn.

Rejection of Claim 6 under 35 U.S.C. 103(a) as allegedly unpatentable over Hein '786 to in view of Stannard et al. '042 in view of Gelbfish '745

Claim 6 indirectly depends from and includes the limitations of Claim 1. Gelbfish '745 does not remedy the above-noted deficiencies of Hein '786 and Stannard et al. '042 with regard to Claim 1. Accordingly, the rejection of Claim 6 over Hein '786 to in view of Stannard et al. '042 in view of Gelbfish '745 is improper and should be withdrawn.

Rejection of Claim 7 under 35 U.S.C. 103(a) as allegedly unpatentable over Hein '786 to in view of Stannard et al. '042 in view of McGrath '665

Claim 7 indirectly depends from and includes the limitations of Claim 1. McGrath '665 does not remedy the above-noted deficiencies of Hein '786 and Stannard et al. '042 with regard to Claim 1. Accordingly, the rejection of Claim 7 over Hein '786 to in view of Stannard et al. '042 in view of McGrath '665 is improper and should be withdrawn.

Claims 8-11 stand objected to as being dependent on a rejected base claim

Claims 8-11 stand objected to as being dependent on a rejected base claim, but would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. In view of the arguments above, the objection is improper and should be withdrawn.

Conclusion

For all of the reasons given above, Appellants respectfully submit that the rejection of Claims 1-7 under 35 U.S.C. 103(a) and objection to Claims 8-11 are improper and should be reversed. It is therefore respectfully requested that the case is in condition for Notice of Allowance and, as such, that the case be remanded to the Examiner for the appropriate action.

Respectfully submitted,



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CLAIMS APPENDIX

1. An apparatus for collecting blood clots, plaque, and other debris in arteries or veins, said apparatus comprising:
 - a filter assembly forming an elongated chamber;
 - a paddle assembly disposed in said chamber comprising at least one paddle having front and rear exterior surfaces defining a thickness of the paddle and pores extending through the thickness of the paddle from the front surface to the rear surface of the paddle;
 - a porous floor disposed within and extending across said chamber; and
 - a means for coupling said filter assembly to an artery and/or to a vein.
2. The apparatus of claim 1, wherein:
 - said paddle assembly includes a rotatable axis and at least two of the paddles extend therefrom; and
 - said pores in said paddles being micro pores.
3. The apparatus of claim 2, wherein said axis extends at a generally perpendicular angle from said porous floor and generally along the axis of said chamber.
4. The apparatus of claim 3, wherein:
 - said chamber is generally cylindrical having a proximal end and a distal end; and
 - said porous floor is disposed adjacent to said distal end.
5. The apparatus of claim 4, wherein said porous floor is structured to allow blood to flow therethrough and to capture debris.
6. The apparatus of claim 5, wherein:
 - said filter assembly includes an anterior wall;
 - said anterior wall having a one-way valve structured to allow blood to flow into said chamber; and
 - said distal end includes a one-way valve structured to allow blood to flow out of said chamber.

7. The apparatus of claim 6, wherein:
said filter assembly includes an engine having a shaft and structured to produce rotation in said shaft; and
said shaft coupled to said axis whereby said axis is rotated.
8. The apparatus of claim 7, wherein said means for coupling said filter to an artery and/or a vein is in fluid communication with said anterior wall one-way valve and said distal end one-way valve.
9. The apparatus of claim 8, wherein said means for coupling said filter to an artery and/or a vein includes:
a guiding catheter in fluid communication with said artery;
a catheter Y-adaptor;
a three-way stopcock;
an inflow tube; and
said guiding catheter, catheter Y-adaptor, three-way stopcock and inflow tube structured to be in fluid communication with each other and said anterior wall one-way valve whereby fluid within said guiding catheter may travel through said Y-adaptor, three-way stopcock and inflow tube into said filter assembly.
10. The apparatus of claim 9, wherein said means for coupling said filter to an artery and/or a vein includes:
an outflow tube in fluid communication with said distal and one-way valve;
a venous Y-adaptor;
a venous sheath in fluid communication with said vein; and
said outflow tube, venous Y-adaptor, and venous sheath structured to be in fluid communication with each other whereby fluid in said filter assembly is returned to said vein.
11. The apparatus of claim 10, wherein:
said guiding catheter has a distal end structured to be inserted in said artery; and
said distal end having an integral balloon.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None